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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,681	12/23/1999	ERIC J. MATHUR	09010/044001	3238
20985	7590	12/18/2003	EXAMINER	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,681

Applicant(s)

MATHUR ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,13-21 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3,4,5,10,11,13-21 and 31-44 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2003 has been entered.

Applicants amendment of claims 1-6, 8-11, 13-20 and 21, the cancellation of claims 29 and 30 and the addition of new claims 31-44, Paper of 10/28/2003, is acknowledged. It is noted that applicants supplied copy of the current claim set does not list claims 29 and 30 as being canceled, but does reference them. Claims 1-11, 13-21 and 31-44 are present for examination.

Applicants' arguments filed on 10/28/2003 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 5-9 and 21 are objected to because of the following informalities:

Claims 21 is a duplicate of claim 16, respectively.

Claim 5 recites "An or recombinant isolated polynucleotide...". This should be "An isolated or recombinant polynucleotide...".

Claims 6-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim (i.e. claim 6 depends from claims 5 and 3 and claim 3 depends from claims 1, 2, 5, 13 and 14). See MPEP § 608.01(n). Accordingly, the claims 6-9 have not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17, 20, 21, and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15-17 (claims 41-43 dependent on claim 15) are drawn to a polynucleotide having a length of at least 15 nucleotides, wherein the nucleotides are contiguous bases of the polynucleotide of claims 1, 14 or 5, respectively and the polynucleotides hybridize with specificity to a polynucleotide that encodes a

phosphatase or its complementary sequence under the specifically defined conditions. Claims 20 and 21 are drawn to similarly claimed polynucleotides and included in this rejection for the same reasons as claims 15-17.

The specification, however, only provides the representative species of claimed polynucleotides represented by SEQ ID NO: 19 and fragments thereof. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of polynucleotides that are claimed is a large variable genus with potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. The specification discloses the species encompassed by SEQ ID NO: 19 of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus which reads on not only polynucleotide fragments of the polynucleotides of claims 1, 14 and 5, but also on polynucleotides encompassed by the claims 1, 14 and 5 but not described by applicants. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 3, 4, 5, 10, 11, 13-21 and 31-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides which encode the amino acid sequence of SEQ ID NO: 28 or enzymatically active fragments thereof, does not reasonably provide enablement for those polynucleotides which merely comprise a sequence that hybridizes under the specified stringent conditions to a polynucleotide that encodes the amino acids of SEQ ID NO: 28 or to a polypeptide having phosphatase activity and having merely 70% identity to the sequence of SEQ ID NO: 28, or a complement thereof.

Claims 5 (claims 3 and 4 dependent on) 10, 11, 13-21 and 31-44 are so broad as to encompass any polypeptide or encoding polynucleotide at least 70% identical to SEQ ID NO: 28 and polynucleotides comprising/having fragments thereof. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides, polynucleotides and methods broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place minimal structural and functional limits on the claimed polynucleotides and polypeptides. Since the nucleic acid sequence of a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the polynucleotides' structure relates to its function. However, in this case the disclosure is limited to those

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polynucleotides that encode the phosphatase having the amino acid sequence of SEQ ID NO: 28.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide with the defined structural limitations, because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without its functional activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue of the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired function and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well

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understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed polynucleotides comprising mere fragments of that polynucleotide which encodes SEQ ID NO: 28. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
12/15/2003